

~~JUN 27 2008~~

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address: Dornier MedTech America, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144 K080959

Contact Person: Theron Gober,
Quality & Regulatory Manager

Phone Number: 770-514-6204

Fax Number: 770-514-6288

Establishment Registration Number: 1037955

Date Prepared: February 23, 2007

Device Trade Name(s): *Medilas D 30 Laser*, model name *Medilas D 1064*

Device Common Name: Diode Laser System

Classification Name: GEX – Laser Instrument, Surgical Powered

Predicate Device(s): The *Dornier Medilas D 1064 Laser* is substantially equivalent in terms of its technological performance to

- *Dornier Medilas D family lasers*, including *Medilas D LiteBeam*, *Medilas D LiteBeam+*, *Medilas D UroBeam*, *Medilas D MultiBeam*, *Medilas D FlexiPulse* (K070536)
- *Diomed Delta 15 and Diomed Delta 30* (K051996)

The *Dornier Medilas D 1064 Laser* is substantially equivalent in terms of its laser wavelength performance to

- *Dornier Medilas Fibertome model 5100* (K964760)
- *Diomed Delta 25* (K063828)
- *Laserscope Lyra Surgical Laser System* (K020021)

General Device Description: The *Dornier Medilas D 1064 Laser* is a continuous-wave diode laser emitting laser radiation in the invisible range of 1064 nm. Each is calibrated during the manufacturing process and during service calls. The end-user does not calibrate fibers for this system. The *Medilas D 1064 Laser* incorporate a graphic display panel, which shows laser operating parameters, application modes, time functions, system status and messages for the user. The *Medilas D 1064 Laser* features several operating modes, including

Standard, Fibertom, LITT and LPS. The laser can be used in contact or non-contact open surgery with or without handpieces.

Intended Use:

The Dornier Medilas D 1064 Laser is indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, ENT, Radiology.

The Dornier Medilas D 1064 Laser is intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes; and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), and in the treatment and/or removal of vascular lesions (tumors).

Technological
Characteristics:

From a clinical perspective and comparing design specifications, the Dornier *Medilas D 1064 Laser* and the predicate devices are substantially equivalent. Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that no significant differences exist between the proposed diode laser and the predicate devices.

Dornier MedTech America, Inc. believes the minor differences of the *Medilas D 1064 Laser* and its predicates lasers should not raise any concerns regarding the overall safety or effectiveness.

Performance Data:

While no performance standards have been established for Diode lasers under Section 514 of the Federal Food, Drug, and Cosmetic Act, the Dornier Medilas D 1064 Laser is in compliance with class IV performance standards for light emitting products promulgated under the Radiation Control for Health and Safety Act of 1968. See 21 C.F.R. §1040.10 and §1040.11. The laser also complies with the applicable requirements of the following voluntary standards: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-22, IEC 60825-1, and European Medical Device Directive (CE).

Conclusion:

Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that the *Medilas D 1064 Laser* and the predicate

devices selected are substantially equivalent and that the differences between the devices are minor which do not raise new issues of safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Dornier Medtech America, Inc.
% Mr. Theron Gober
Quality and Regulatory Manager
1155 Roberts Boulevard, Suite 100
Kennesaw, Georgia 30144

Re: K080959

Trade/Device Name: Medilas D 1064 Laser

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: II

Product Code: GEX

Dated: June 9, 2008

Received: June 10, 2008

Dear Mr. Gober:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080959

Device Name: Medilas D 1064 Laser

Indications for Use:

The *Dornier Medilas D 1064 Laser* model (trade name *Medilas D30*) is indicated for use in medicine and surgery, in the following medical specialties:

- Urology
- Plastic Surgery
- General Surgery
- Dermatology
- Gynecology
- Pulmonary Surgery
- Neurosurgery
- Gastroenterology
- ENT
- Radiology

The *Dornier Medilas D 1064 Laser* model (trade name *Medilas D30*) is intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), and in the treatment and/or removal of vascular lesions (tumors).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080959